UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,557	11/30/2004	Roger Bonnert	06275-423US1	7055

26164 7590 03/02/2006

FISH & RICHARDSON P.C.
P.O BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
BARKER, MICHAEL P	
ART UNIT	**PAPER NUMBER**
1626	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/516,557	BONNERT ET AL.	
	Examiner	Art Unit	
	Michael P. Barker	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5;7-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5 and 9* is/are allowed.

6)☒ Claim(s) *1-3;7* is/are rejected.

7)☒ Claim(s) *4 and 8* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/30/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *1*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 and **7-9** are pending in this application. **Claims 1-3** and **7** are rejected. **Claims 4** and **8** are objected to.

Priority

This application is a 371 of PCT/SE03/00856, filed May 27, 2003 and claims foreign priority to Swedish Application No. 0201635-0, filed May 30, 2002.

Information Disclosure Statement

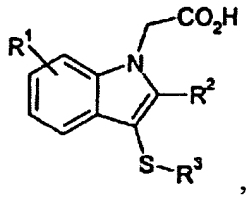
The information disclosure statement (IDS) submitted on November 30, 2004 was correctly filed. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the examiner. Please refer to Applicant's copy of PTO-1449 submitted herewith.

Claim Rejections - 35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Luscher et al., "Deblocking of o-Nitrophenylsufenyl-Protected Peptides by Ammonium Thiocyanate and (2-Methyl-1-indolyl)acetic acid", Helv. Chim. Acta 66(2):602-605 (1983). Specifically, Luscher teaches the compound (2-methyl-3-(2-nitrophenylthio)-1-indolyl)acetic acid at p. 602 in the "Summary"; p. 603 in the text between Tables 1 and 2; and p. 604 under "Experimental Part". Applicant's **Claims 1-3** are anticipated by the Luscher reference in that these claims teach a

compound of the general formula (I),  , wherein $\mathbf{R^1}$ is hydrogen; $\mathbf{R^2}$ is C_{1-7} alkyl; and $\mathbf{R^3}$ is an aryl group substituted by nitro. This rejection can be overcome via a proviso to Claim 1 obviating the situation in which Applicant's claims result in a compound disclosed by Luscher, et al.

Claim Rejections - 35 USC § 112 1st ¶

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a patient with asthma or rhinitis, does not reasonably provide enablement for every disease mediated by prostaglandin D2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in MPEP 2164.01(a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue."

In re Wands, set forth the following eight factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph:

1. The nature of the invention;
2. The state of the prior art;
3. The predictability or lack thereof in the art;
4. The amount of direction or guidance present;

5. The presence or absence of working examples;
6. The breadth of the claims;
7. The quantity of experimentation needed; and
8. The level of the skill in the art.

8 USPQ2d 1400 (1988).

The nature of the invention

The nature of the invention is a "method of treating a disease mediated by prostaglandin D2, which comprises administering to a patient a therapeutically effective amount of a compound of formula (I), or a pharmaceutically acceptable salt as defined in claim 1."

The state of the prior art and the predictability or lack thereof in the art

The state of the prior art, pharmacology, involves screening in vitro and in vivo to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. Because of the nature of unpredictability, it is highly unlikely that the contemporary knowledge in the art would allow one of ordinary skill in this art to accept the instantly claimed compounds or pharmaceutical compositions thereof as treating any disease or disorder mediated by prostaglandin D2.

The amount of direction or guidance present and presence or absence of working examples

There is no direction or guidance provided which supports Applicant's claimed method for the treating of any disease or disorder for which mediation of prostaglandin D2 is indicated. The only direction or guidance present in Applicant's Specification for a method for using compounds and compositions of Formula I to treat clinical conditions in which a prostaglandin D2 is indicated is found on pp. 12-15 and 47-48.

Pages 12-15 of Applicant's Specification reference specific diseases which are mediated by prostaglandin D2. However, Applicant's Specification does not provide support for the use of

substituted indoles in treating *any* clinical condition in a mammal for which mediation of prostaglandin D2 is indicated.

The breadth of the claims, quantity of experimentation, and level of skill in the art

Claim 7 is drawn (in part) to "A method of treating a disease mediated by prostaglandin D2, which comprises administering to a patient a therapeutically effective amount of a compound of formula (I), or a pharmaceutically acceptable salt as defined in claim 1." While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed to enable one skilled in the art to use Applicant's claimed compounds in treating any disease in which mediation of prostaglandin D2 is indicated is undue. With no direction or guidance from Applicant's Specification, one of skill in the art would need to determine every disease associated with prostaglandin D2, identify subjects with such diseases, administer Applicant's claimed invention, and then demonstrate that if the identified subject showed signs of overcoming such a disease, such an effect was the direct result of administration of Applicant's claimed invention.

Because of the aforementioned reasons, a person of skill in the art could not practice the claimed invention herein, or a person of skill in the art could practice the claimed invention herein only with undue experimentation and with no assurance of success.

This rejection can be overcome by incorporating into **Claim 7** specific diseases associated with prostaglandin D2 found throughout the Specification and most notably in Claim 8.

Claim Objections

Claims 4 and **8** are objected to for being based on rejected base claims.

References Cited

If a copy of a provisional application listed on the bottom portion of the accompanying Notice of References Cited (PTO-892) form is not included with this Office action and the PTO-892 has been annotated to indicated the copy was not readily available, the copy could not be readily obtained when the Office action was mailed. Should Applicant desire a copy of such a provisional application, Applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless Applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael P. Barker whose telephone number is (571) 272-4341. The examiner can normally be reached on Monday-Friday 8:00 AM- 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699. The unofficial fax phone for this group are (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate the Header (upper right) "Official" for papers that are to be entered into the file, and " Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Michael P. Barker
Patent Examiner, AU 1626

Technology Center 1600

(for) Joseph McKane
Supervisory Patent Examiner, AU 1626

Technology Center 1600